OCCIPITAL PLATE AND SYSTEM FOR SPINAL STABILIZATION

FIELD OF THE INVENTION

The present invention is related to a system for stabilizing the spine. More particularly, the present invention is related to an occipitocervical fixation system that is mounted to both the occiput and spine.

BACKGROUND OF THE INVENTION

Occipitocervical fixation has been achieved using a variety of techniques which generally provide stabilization of the base of the skull with respect to the neck. In order to promote fusion, for example, bone struts formed of autogenous ribs or curved iliac crest struts have been fixed to the occiput and spinous processes, cervical laminae, or facets. Wires are used to fix the struts in place until bone fusion occurs. The thickness of the occiput varies, however, and thus the occiput is typically wired in regions of greater thickness such as near the foramen magnum, at the nuchal line, and along the midline crest. Holes are drilled in the occiput to receive the wires that are also fed through holes in the struts. Although bone fusion occurs with this technique, the struts may be weak prior to fusion, and additional orthosis is applied such as with a halo vest or other hard collar until the struts can provide acceptably strong immobilization. Alternatively, metal struts may be used.

Other techniques for occipitocervical fixation involve the use of other metal implants. One metal implant is a stainless steel, U-shaped device known as a Steinman pin. The threaded pin is bent to match the contour of the occipitocervical region, and fixed to the occiput and cervical laminae or facets using wires. The pin is generally symmetrically disposed about the spine, with the sides of the "U" creating a central region in which a bone graft can be disposed and further wired to the pin. When attached to the occiput and spine, the pin assumes an inverted-U configuration. Several holes are formed in the occiput so that the U-bend may be fixed in place.

Additional metal implants include grooved or roughened titanium rods, smooth steel rods in the form of a Hartshill rectangle or Ransford loop, a Cotrel-Dubousset rod screw plate, and titanium frames have been employed.

Despite these developments, there exists a need for an occipital plate and system for spinal stabilization in which the plate and rod components are separated to permit greater flexibility in installation by the surgeon. In particular, because a traditional

unitary plate and rod system is bent in two planes in order to properly adjust it with respect to the occiput, such a unitary design presents difficulties in achieving the desired fit. devices Fixation is using wires that extend through holes formed in the occiput.

SUMMARY OF THE INVENTION

The present invention is related to an occipital plate that includes a Y-shaped plate portion having a front side and a back side, a central portion, two leg portions, and a plurality of bone screw holes in the central portion, the holes being configured and dimensioned to receive a bushing. The occipital plate also includes at least one clamping portion disposed on the front side proximate a free end of at least one of the leg portions, and the plate is bendable to conform to the an occiput. In one embodiment, the central portion includes an upper portion, a lower portion, and a grooved portion therebetween, the upper portion having one bone screw hole. The grooved portion is flexible to permit the upper portion to be disposed at an angle with respect to the lower portion. The leg portions and at least a portion of the central portion are disposed in nonparallel planes, and the planes may intersect at an angle of between about 160° and about 175°, and in one embodiment the planes intersect at an angle of about 170°.

The clamping portion may include a pivot member and a clamp plate, the clamp plate being pivotable about the pivot member. The clamp plate may further include a hole, the pivot member being received in the hole. The pivot member also may include a tapered portion with serrations, and the leg portion may further include a tapered hole with serrations, with the serrations of the tapered portion positively engaging the serrations of the tapered hole. The diameter of the tapered hole increases from the back side to the front side, and the clamp plate is secured to the pivot member with a fastener. The leg portion additionally includes a rod-receiving first recess and the clamping plate additionally includes a rod-receiving second recess, with the first and second recesses generally opposing each other and the second recess being serrated. The bone screw holes in the lower portion may be disposed in a rectangular array, and at least one group of bone screw holes in the array may be disposed along a central axis of the plate extending between the leg portions. The bone screw hole in the upper portion may be disposed on the central axis, and at least two bone screw holes may be disposed coaxially. In one embodiment, the bushings permit polyaxial angulation, the plate is bendable along at least two generally parallel axes and/or at least two generally perpendicular axes.

The present invention is also related to an occipitocervical fixation system including an occipital plate having at least one rod clamp portion and a plate portion with at least one hole for receiving a bone screw, the rod clamp portion having a post, a clamp plate

with a hole for receiving the post, and a fastener for tightening the clamp to the post. The system also includes at least one bone screw and at least one rod, with the rod being retained between the plate portion and the clamp plate and being pivotable about the post.

Furthermore, the present invention is related to a pre-bent rod for attachment to an occipital plate including a straight section, a bent section, and a serrated clamping section, with the straight section and the serrated clamping section being disposed substantially perpendicular to each other, and the serrated clamping section and the bent section being disposed at an angle of about 45° with respect to each other. In one embodiment, the serrated clamping section is generally cylindrical and includes circumferential serrations about an angular range of between about 90° and 180°.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred features of the present invention are disclosed in the accompanying drawings, wherein similar reference characters denote similar elements throughout the several views, and wherein:

FIG. 1 shows a front view of an occipital plate according to the present invention;

FIG. 2 shows a side view thereof;

FIG. 3 shows a partial cross-sectional side view of a hole in the occipital plate of FIG. 1 taken along line III-III;

FIG. 4 shows another front view of the occipital plate of FIG. 1 without clamping plates attached thereto;

FIGS. 4A-4B show front views of additional embodiments of occipital plates without clamping plates attached thereto;

FIG. 5 shows a partial cross-sectional side view of a leg portion of the occipital plate of FIG. 4 taken along line V-V;

FIG. 6 shows a partial front view of part of a leg portion of the occipital plate of FIG. 4;

FIG. 7 shows a side view of the occipital plate of FIG. 4;

FIG. 8 shows a post according to the present invention;

FIG. 9 shows a side view of the occipital plate of FIG. 7 with a post inserted therein;

FIGS. 11-14 show a top view, bottom view, side view, and partial cross-sectional view, respectively, of a clamping plate according to the present invention;

FIGS. 15-18 show a perspective view, top view, partial cross-sectional view through line XVII-XVII, and partial cross-sectional view through line XVIII-XVIII, respectively, of a bushing for use with the present invention;

FIGS. 19 and 19A show a front view of a first embodiment of a right pre-bent rod and a left pre-bent rod, respectively, according to the present invention;

FIG. 20 shows a side view of the pre-bent rod of FIG. 19;

FIG. 21 shows a side view of the serrated clamping section of FIG. 20;

FIGS. 22-23 show a front view and a side view of a second embodiment of a pre-bent rod according to the present invention;

FIG. 24 shows an occipital plate with first and second embodiments of the pre-bent rods of FIGS. 19-23;

FIGS. 25-26 show a front view and a partial cross-sectional side view of another embodiment of an occipital plate according to the present invention;

FIGS. 27-29 show a front view side view, and partial cross-sectional side view of yet another embodiment of an occipital plate according to the present invention; and

FIGS. 30-31 show perspective view of additional embodiments of occipital plates according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring initially to FIGS. 1-3, an occipital plate 10 according to the present invention is shown. In the preferred embodiment, occipital plate 10 is generally Y-shaped with a pair of rod supporting arms 12, 14 and a central extension 16 along with a main portion 17. Holes 18 extending from the front surface 11 to the back surface 13 are provided for receiving bone fasteners (not shown) for fixation of occipital plate 10 to the occiput. Preferably, as shown in FIG. 3, holes 18 are each provided with an expansion head bushing 20 to permit relative angulation of a locking screw or other bone fastener received therein. A grooved region 22 is provided along central extension 16 to facilitate bending of plate 10. In the preferred embodiment, plate 10 may be bent along grooved region 22. In an alternate embodiment, central extension 16 and grooved region 22 may be removed from plate 10. Preferably, grooved region 22 has a thickness that may be accommodated in a rod cutter as used with the rods of the present invention. A clamp assembly 24, 26 is provided proximate the free end of each rod supporting arm 12, 14, respectively, for clamping a portion of a rod against occipital plate 10. Preferably, spinal rods are positionable in clamp assemblies 24, 26, by insertion from the top portion 21of the assemblies. Alternatively, the rods may be inserted from a side portion 23 of the assemblies. In addition, although the

preferred embodiment includes two clamp assemblies, 24, 26, a number other than two may be provided. Rod supporting arms 12, 14 may also be bent, for example near points 12', 14'.

As shown in FIG. 4, preferably occipital plate 10 includes seven fastener holes 18, with six of the holes 18 aligned in a 2 × 3 rectangular array. Three holes 18 are aligned along line 28 while three holes 18 are aligned along line 30, with lines 28, 30 being parallel to each other. In addition, while three holes 18are aligned along central line 32, two holes are aligned long each of lines 34, 26. Lines 32, 34, 36 are parallel to each other and perpendicular to lines 28, 30. In addition, grooved region 22 is aligned along a line 38 which is parallel to lines 28, 30.

As shown in FIGS. 4A and 4B, additional hole patterns may be used with the occipital plates of the present invention. For example, in FIG. 4A, occipital plate 10' includes four holes 18 that are disposed adjacent line 32, such that the plate may be bent along line 32 without bending along holes 18. In addition, this permits bone screws inserted in holes 18 to be angulated toward the midline 32 of the plate. In FIG. 4B, occipital plate 10" includes a triangular array of holes 18 with one hole along line 28' and another hole along line 30'.

Referring particularly to FIGS. 5-6, occipital plate 10 includes holes 38, 40 in lower portions 42, 44 respectively. Holes 38, 40 are configured and dimensioned to receive clamping posts, as will be described. Rod-receiving recesses 46, 48 are generally V-shaped, with each leg of the "V" extending at an angle θ_1 with respect to a line 50 extending through V-notch 52 and the center of hole 40, and further aligned parallel to lines 32, 34, 36. In the preferred embodiment, angle θ_1 is between about 60° and about 80°, and more preferably about 70°. Arcuate stepped-in portions 54, 56 are disposed along the lowermost regions of rod supporting arms 12, 14, and preferably extend through a total angle of about 80° and about 120°, and more preferably about 100°, symmetrically with respect to line 50. As shown in FIG. 5, holes 38, 40 are preferably tapered with a first diameter D_1 on front surface 11 being smaller than a second diameter D_2 on back surface 13.

With reference to FIG. 7, central extension 16 is disposed along a plane 60, while rod supporting arms 12, 14 are disposed along a plane 62. Planes 60, 62 are not coplanar, and form an angle θ_3 with respect to each other that is preferably between about 160° and about 175°, and more preferably about 170°.

Turning to FIGS. 8-10, a post 64 is shown. One post 64 is placed in each hole 38, 40 such that the tapered head 66 rests in the hole. Preferably, taper head 66 tapers at an angle θ_4 of between about 5° and 15° and more preferably about 10° with respect to the central axis 70 of post 64, and this taper angle is also present in holes 38, 40. A post 64 installed in a hole 38 is shown in FIGS. 9-10. Preferably, head 66 is provided with

serrations that interlock with serrations on the inside surface of a hole 38, 40 so that a positive mechanical engagement can be achieved to assist in locking a post 64 in place with respect to the occipital plate 10. Post 64 also includes a body portion 68, which preferably is at least partially threaded for receiving a nut or other like-threaded fastening device.

Referring to FIGS. 11-14, a clamp plate 72 for use as a part of a clamp assembly 24, 26 is shown. Clamp plate 72 includes a hooked serrated portion 74 for engagement with a longitudinal rod, and further includes a central pivoting hole 76 in which a post 64 is received. A leg 78 of each clamp plate 72 is received in an arcuate stepped-in portion 54, 56 of a rod supporting arm 12, 14. Front edge 80 of clamp plate 72 is disposed at an angle θ_5 with respect to top edge 82, and preferably angle θ_5 is about 45°. Back edge 84 is disposed at an angle θ_6 with respect to rear edge 86, and preferably angle θ_6 is about 38°. Outer and inner sides 88, 90, respectively, are substantially parallel with respect to each other. Edge 92 is disposed at an angle θ_7 with respect to edge 93, with angle θ_7 preferably being about 22°.

Turning briefly to FIGS. 15-18, a bushing 20 for use with the present invention is shown. Bushing 20 has an upper surface 116, a lower surface 118, and a sidewall 120. Sidewall 120 has an exterior surface 122 configured and dimensioned for polyaxial rotation within a through hole 18. As a result and as described in more detail below, a fastener inserted through a bore 124, which is defined by an interior surface 126 of bushing 20 and extends through both upper and lower surfaces 116, 118, can be inserted at a wide variety of orientations relative to occipital plate 10. In an exemplary embodiment, bushing 20 has a frustospherical shape. Alternatively, bushing 20 can have a frustoconical shape. With either shape, bore 124 can extend through the central longitudinal axis perpendicular to the parallel upper and lower surfaces 116, 118.

Bushing 20 includes slots 128 located on sidewall 120. Slots 128 allow sidewall 120 to expand outwardly against through hole 18. This outward expansion locks bushing 20 at the selected orientation relative to the axis of through hole 18. In order to enhance the locking effect upon expansion, exterior surface 122 of sidewall 120 and/or the periphery of through holes 18 can be provided with ridges 130. Ridges 130 provide an additional mechanism to resist motion of bushing 20 relative to occipital plate 10 once sidewall 120 has expanded outwardly. Although bushing 20 is shown having four slots, any number of slots, including one, can be used as long as the chosen number of slots provides for outward expansion of sidewall 120. Slot 128a extends from upper surface 116 through lower surface 118 while the rest of slots 128 do not extend through to lower surface 118. Slots 128 all extend from upper surface 116 of bushing 20.

In the preferred embodiment, pre-bent rods suitable for use with the present invention are shown in FIGS. 19-21. Each rod 140 includes a straight section 142 for running generally parallel to the spine, a bent section 144, and a serrated clamping section 146. Sections 142, 146 are substantially perpendicular to each other, while sections 144, 146 are disposed at an angle θ_8 with respect to each other. Preferably, angle θ_8 is between about 40° and about 50°, and more preferably approximately 45°. As shown in FIG. 21, serrated clamping section 146 includes serrations 148 about a portion of its circumference. When bent section 144 is aligned with vertical line 150, and section 146 is centered at the intersection of perpendicular lines 150, 152, it can be seen from FIG. 21 that serrations 148 only extend through an angle θ_9 from line 152. Preferably, angle θ_9 is between about 30° and about 50°, and more preferably about 41°. Moreover, serrations 148 are present along the circumference of section 146 of rod 148 through a total angular range θ_{10} as measured from center point 154. Preferably, θ_{10} is between about 90° and 180°, and more preferably θ_{10} is about 156°.

The pair of rods used with occipital plate 10 are typically mirror images of each other. For example, a rod 140 would be used with right clamp assembly 26 while a mirror image of rod 140, as shown in FIG. 19A, would be used with left clamp assembly 24.

In an alternate embodiment shown in FIGS. 22-23, pre-bent rod 160 includes a straight section 162 for running generally parallel to the spine, a transition section 164, and a serrated clamping section 166. Sections 162, 166 are substantially perpendicular to each other, while sections 164, 166 are disposed at an angle θ_{11} with respect to each other. Preferably, angle θ_{11} is between about 40° and about 50°, and more preferably approximately 45°.

Pre-bent rods 140, 160 are shown retained in clamp assemblies 24, 26, respectively, in FIG. 24. Although the pair of rods used with occipital plate 10 are typically mirror images of each other, for illustrative purposes only, one of each rod 140, 160 is shown. As seen particularly with regard to clamp assembly 24, clamp plate 72 rotates about post 64, and may be fixed in place using a nut 168. Rod receiving recesses 46, 48 are used to further lock a rod 140, 160 in place.

Alternate embodiments of occipital plates are shown in FIGS. 25-31. First referring to FIGS. 25-26, similar to occipital plate 10, occipital plate 200 includes seven holes 18 for receiving bone fasteners. However, in this embodiment, holes 18 are disposed about four parallel lines 202, 204, 206, 208 instead of three. In addition, as shown particularly in FIG. 26, pre-bent rods are clamped to occipital plate 200 using set screws 210 extending through a U-shaped or C-shaped section 216, and which are disposed about

an axis 212 that may be aligned with or slightly offset from the center of a rod held in region 214. Another embodiment is shown in FIGS. 27-29, in which an occipital plate 250 is provided with nine holes 18 disposed about four parallel lines 254, 256, 258, 260. As with occipital plate 200, sections 262 are provided for clamping spinal fixation rods to occipital plate 250. A threaded set screw (not shown) is threadably received in like-threaded hole 264, which is preferably aligned along an axis 266 disposed at an angle θ_{12} with respect to plate wall 268. Preferably, angle θ_{12} is between about 50° and about 70°, and more preferably about 60°. Again, threaded hole 264 aligns a set screw to be offset from the center of a rod seated in region 270 and centered about point 272.

Additional embodiments of occipital plates are shown in FIGS. 30-31. Notably, expansion head screws 282 are shown installed or partially installed in plate holes 18. Occipital plates 280, 300 include notched regions 284, 302, respectively, to facilitate bending. Also, side clamping assemblies 286, 304 receive rods 290, 308 that are fixed with a set screw extending in holes 288, 306, respectively. Preferably, side clamping assemblies 286, 304 are angulated such that rods 290, 308 are disposed at an angle of between about 20° and about 30°, and more preferably about 25°with respect to the plane of the plate prior to bending.

In some preferred embodiments of the present invention, cylindrical rods with a diameter of 3.5 mm are used as the spinal rods or pre-bent rods. In alternate embodiments, straight rods may be used and oriented accordingly by a surgeon using a rod bender.

In the occipital plate designs disclosed herein, screw holes have been positioned along the midline of the plate for use at the midline of the occiput, since the bone thickness there is greater than on the sides. In some embodiments, the screw holes may be angled about 12° to facilitate access to the screws with a screwdriver, and to enhance pull-out strength of the screws due to the wedge effect. Although expansion head screws are preferred, other non-locking screws may be used. Arc shaped cuts between the clamping assemblies or arrangements of each plate allow the placement of a bone graft. In the preferred embodiment, occipital plate 10 is formed of titanium. Preferably, the shape of the occipital plate facilitates polyaxial bending thereof.

The number of holes provided in an occipital plate of the present invention for receiving bone screws may be varied, as may the pattern of the holes and the relative alignment. Other screw hole shapes such as an oval shape, and other hole sizes may be used, as well as alternative means for locking screws. Bushings may not be included in some embodiments. Alternative fasteners for attaching an occipital plate to bone include staples and wires.

While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination thereof. Therefore, this invention is not to be limited to only the specifically preferred embodiments depicted herein.

Further, it should be understood that variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains. For example, the C-shaped clamping sections of some embodiments of the occipital plate may instead include full-circle regions for receiving rods. In another embodiment, a sleeve for receiving the rods may extend across some or the entire the length of the occipital plate. In yet another embodiment, two smaller occipital plates are provided for securement to the occiput, with each plate having a single clamp assembly and receiving one rod. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present invention are to be included as further embodiments of the present invention. The scope of the present invention is accordingly defined as set forth in the appended claims.